



REMARKS

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Patent  
252/029

Claim 13 is pending in the present application. Claim 13 has been amended and claims 15 - 23 have been added by this Amendment. New claims 15 - 23 are fully supported by the specification, e.g. pgs. 31 - 34. No new matter is added by this Amendment.

Claim 13 has been objected to on the ground that "the claim fails to reflect the restriction requirement and election set forth in paper nos. 7 and 9." Claim 13 has been amended to reflect the election made in response to the restriction requirement. Accordingly, Applicants respectfully respect withdrawal of the objection.

Claim 13 has been rejected under 35 USC §103(a). Reconsideration and withdrawal of the rejection is respectfully requested in view of the foregoing amendments and the following remarks.

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I. Rejection under 35 USC §103(a).

At the time the invention was made, the subject matter of the pending application was subject to an obligation of assignment to Zengen, Inc. The assignment has been recorded at the USPTO: the recordation date is 08/08/2000, the reel/frame is 010982/0713.

Claim 13 has been rejected as being unpatentable over Lipton (1992), Reg. No. 5157023 ("Lipton"). The Office Action states, "Lipton teaches that tripeptides bearing the amino acid sequence KPV are efficient antipyretic or antiinflammatory compounds useful for the treatment of bacterial infections (see Abstract). ... [I]t would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to treat HIV-infected patients suffering from secondary infections with the compounds of Lipton (1992), since this would

reduce the fever and swelling associated with such opportunistic infections.” Applicants respectfully traverse.

First, the Lipton patent does not teach that tripeptides with the amino acid sequence KPV are useful for treatment of *bacterial infections*. Contrary to the statement in the Office Action, the Abstract does not disclose treatment of ‘bacterial infections’ with peptides containing KPV. The words ‘bacterial’ and ‘infection’ do not even appear in the Abstract. In addition, the Specification and Claims of the Lipton patent do not describe or even mention the treatment of ‘bacterial infections’ using peptides containing KPV. Instead, the Lipton patent describes a method for using KPV to reduce fever and inflammation (see Abstract). There is nothing in the Lipton patent that teaches or suggests that peptides containing KPV have anti-microbial or anti-infection properties. Moreover, there is nothing in the Lipton patent that teaches or suggests use of peptides containing KPV to treat infection. The Office Action admits that the Lipton patent “does not disclose the administration of these compounds to HIV-infected patients suffering from secondary infections.” As a result, it would not have been obvious to use KPV peptides of the Lipton patent to treat infections in general. And further, it would not have been obvious to use KPV peptides to treat secondary infections of HIV-infected individuals.

In addition to the failure of the Lipton patent to disclose the anti-microbial/infection properties of compounds containing KPV, the Lipton patent teaches away from using the present invention to treat infections. In the Lipton patent, the anti-inflammatory properties of compounds containing KPV are compared to those of hydrocortisone (an accepted standard for anti-inflammatory activity). It was determined that the anti-inflammatory properties of compounds containing KPV were commensurate with those for hydrocortisone. The Lipton patent states that the results of their experiments

“indicated that the tripeptide inhibits inflammation as well as the classic anti-inflammatory agent, when given in an equal dose by weight, albeit with a slight difference in time course. Based on the present results and the known effects of hydrocortisone and inflammation in man, it is concluded that the tripeptide Lys-Pro-Val can be used to reduce inflammation in man, in dosage not markedly different from that of hydrocortisone.” Page 11, line 63 – p. 13, line 2.

It was well known to one skilled in the art at the time of the invention that anti-inflammatory compounds, such as hydrocortisone, suppress an individual's immune system and, as a result, increase the individual's risk of infection. Thus, since compounds containing KPV exhibit anti-inflammatory properties similar to those in hydrocortisone, it would not have been obvious to treat individuals suffering from an infection with compounds containing KPV in view of the understanding that hydrocortisone should not be used to treat an individual suffering from an infection.

In addition, some researchers have used hydrocortisone to stimulate the growth of the AIDS virus in the laboratory while others have determined that hydrocortisone enhances the expression of HTLV-III. Markham et al., *Hydrocortisone and some other hormones enhance the expression of HTLV-III*, Int'l J. Cancer, 37(1):67-72 (1986), a copy has been enclosed with the response. As a result, it would not have been obvious to use compounds containing KPV to treat HIV patients infected with secondary infections in view of the disclosure in the Lipton patent.

At the time of the invention, one skilled in the art would not have used the compounds of the Lipton patent to treat infections since it was known that anti-inflammatory compounds, such as hydrocortisone, increase the risk of infection. Thus,

the Lipton patent teaches away from using compounds containing KPV to treat infections. Accordingly, it would not have been prima facie obvious at the time of the invention to treat HIV-infected patients suffering from secondary infections with the anti-inflammatory compounds of the Lipton patent. Thus, withdrawal of the rejection under 35 USC § 103(a) is respectfully requested.

### **CONCLUSION**

Applicants respectfully submit the above Amendment including (1) a clean version of the rewritten amended claims in accord with 37 CFR §1.121(c)(1)(i) and (2) a marked-up version of the rewritten amended claims in accord with 37 CFR §1.121(c)(1)(ii). Applicants respectfully request the Examiner to enter this amendment.

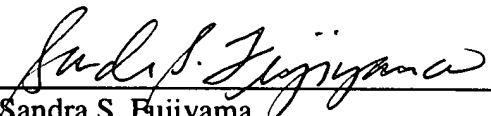
In view of the foregoing, it is submitted that the claims are allowable, and issuance of a Notice of Allowance is requested. Applicants hereby request a one-month extension of time. The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Lyon & Lyon's Deposit Account No. 12-2475. If Applicants can do anything more to expedite this application, Applicants ask the Examiner to contact the undersigned at (213) 489-1600.

Respectfully submitted,

LYON & LYON LLP

Dated: April 18, 2002

By:

  
Sandra S. Fujiyama  
Reg. No. 46,713



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PATENT TRADEMARK OFFICE

LYON & LYON LLP  
Suite 4700  
633 W. Fifth Street  
Los Angeles, CA 90071  
Tel: (213) 489-1600  
Fax: (213) 955-0440